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B5A AB13 AB14 AB18 A1R214B A1R314C1C A1R314C1X A1R322 A1R449 A2E4H A20T14

(56) Documents Cited
GB 2328395 A **GB 2273678 A**
GB 1126535 A **WO 97/03800 A1**

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(54) Abstract Title
Moulded anatomical mask

(57) An anatomical mask (20) is manufactured by injection moulding a first polymer in a central region (11) of the mould 10, allowing it to cool and then injection moulding into an outer region (9) of the mould a second, elastomeric polymer containing a foaming agent. Once the second polymer has bonded to the periphery of the shell (13) formed by the first polymer the mould is opened allowing the second polymer to inflate to form a cushion (15).

A tubular metal barrier member 6 is movable in a tubular slot 16 between a closed position (figure 2), in which region 11 is separated from region 9, and withdrawn position to allow bonding of the second polymer (thermoplastic elastomer) to the periphery of shell 13 (transparent polypropylene).

Gas from a source other than the foaming agent may be introduced into the cushion material before the latter has solidified.

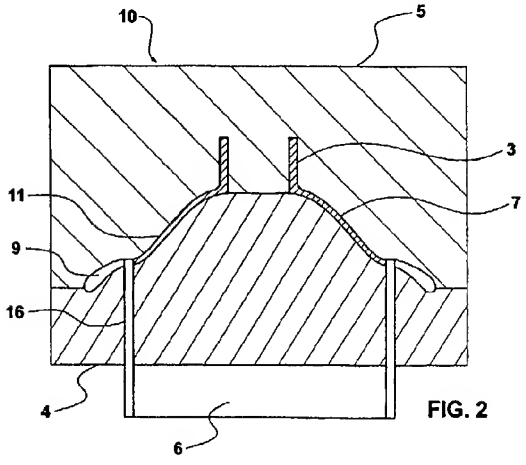

FIG. 2

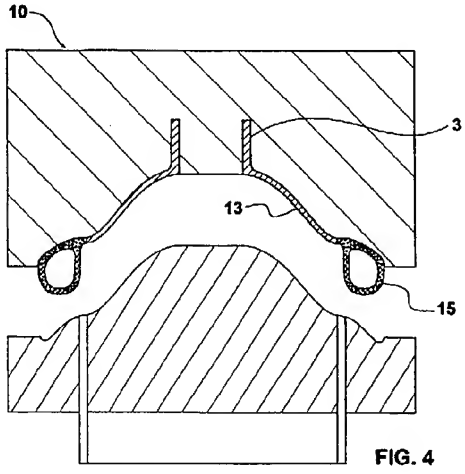

FIG. 4

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At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

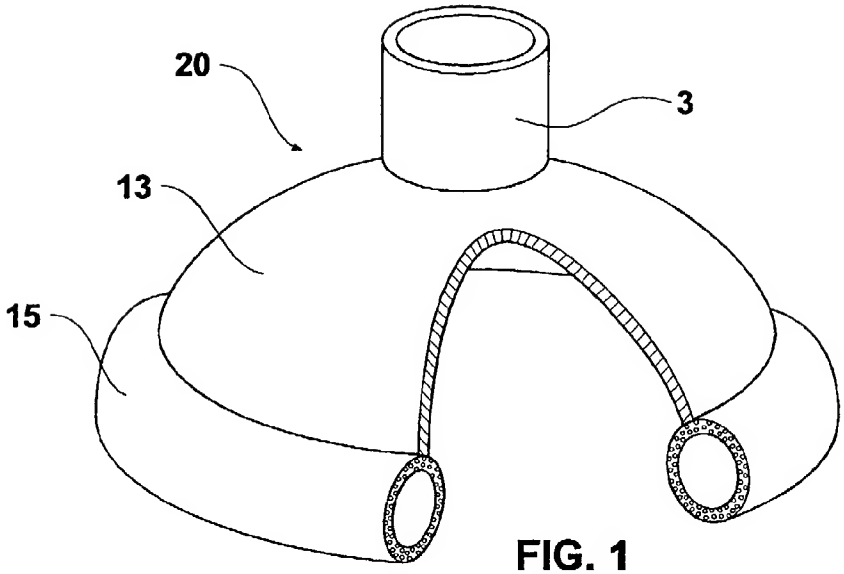

FIG. 1

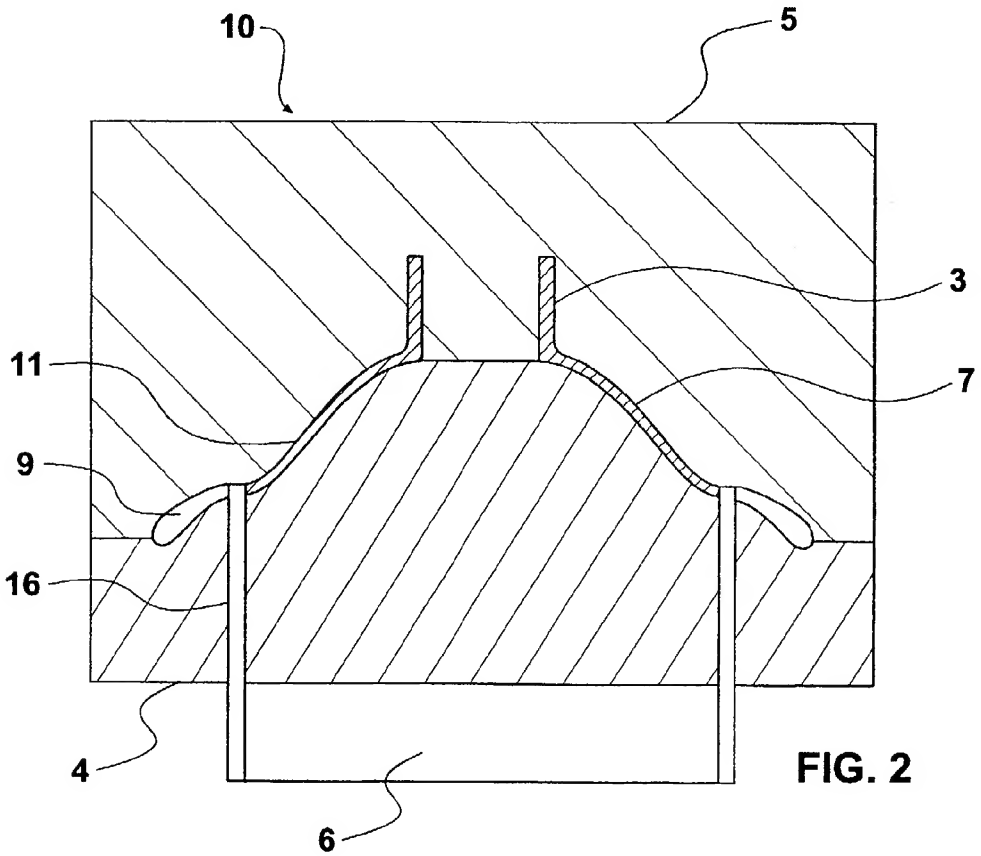

FIG. 2

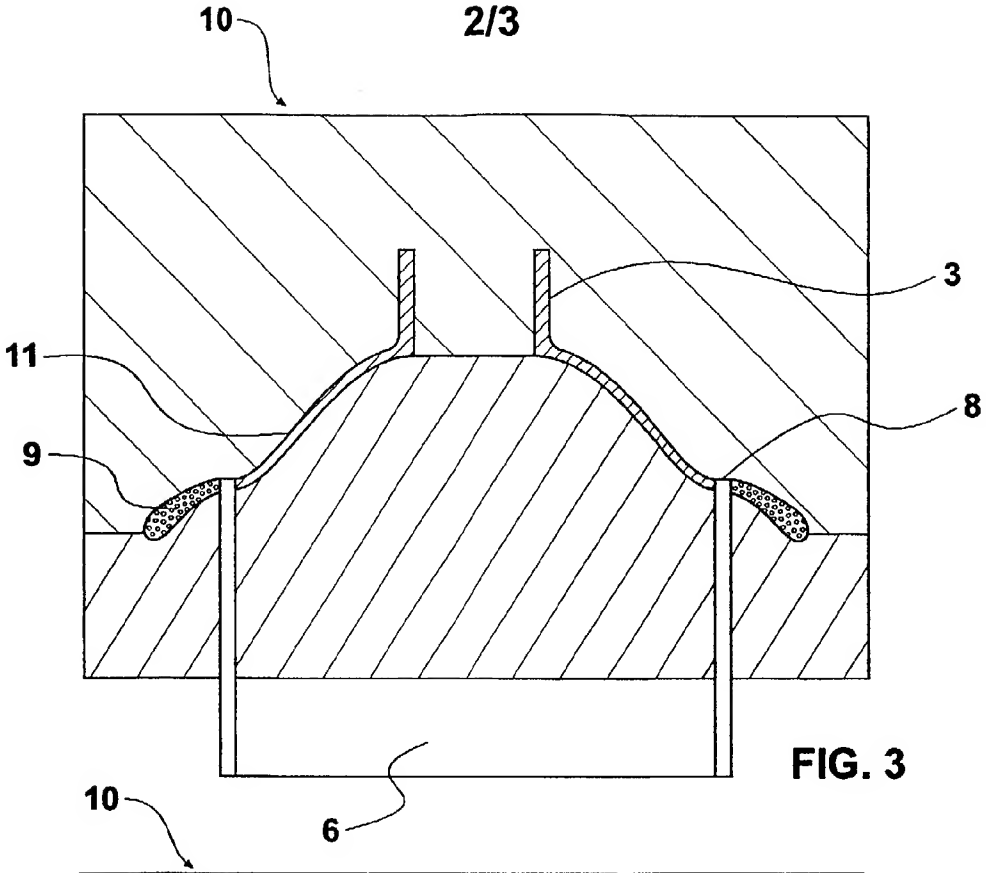

FIG. 3

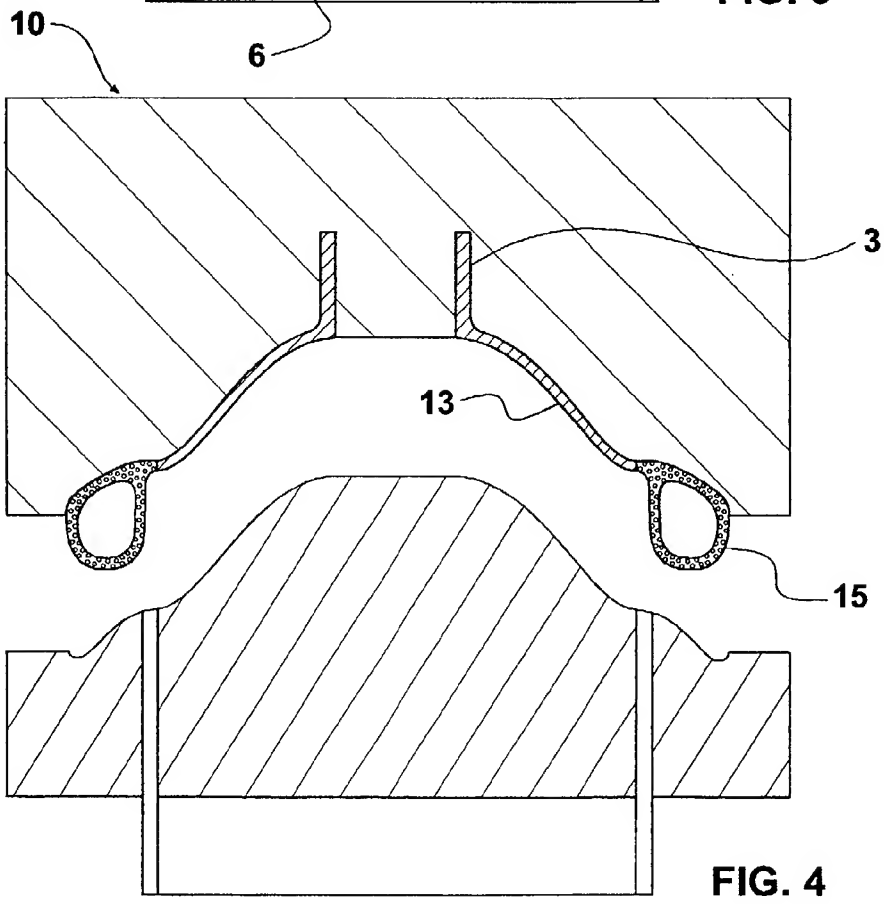

FIG. 4

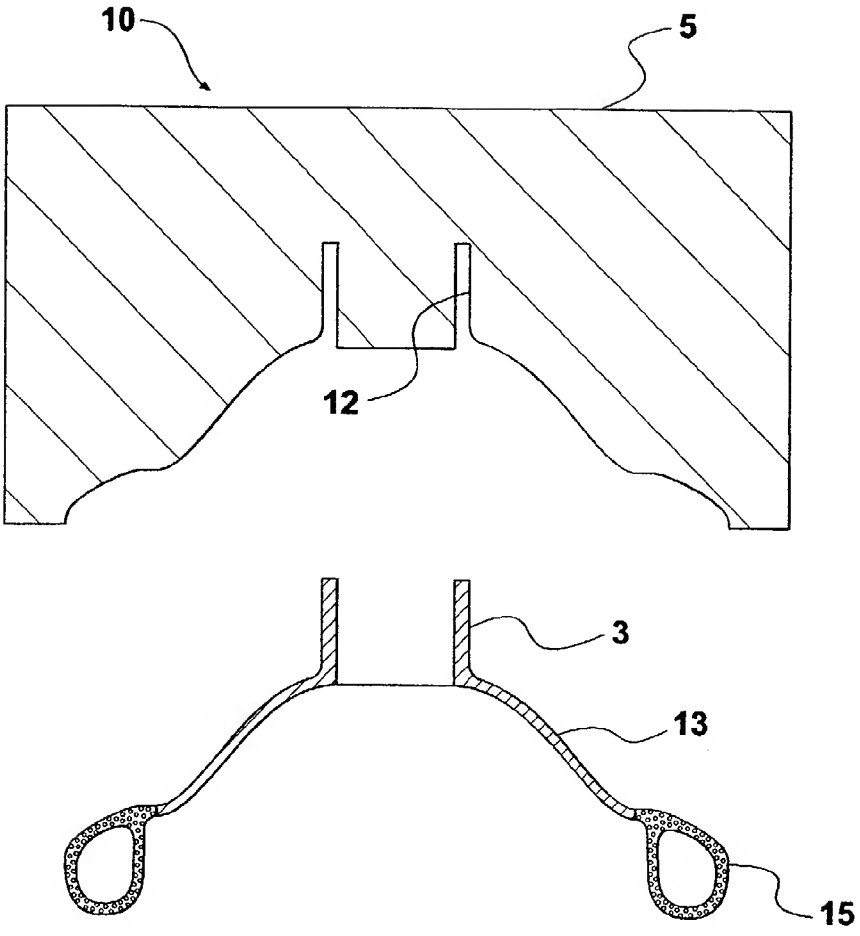

FIG. 5

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"ANATOMICAL MASK"

This invention relates to an improved anatomical mask and method of manufacturing the same. Examples of such masks are face masks designed to cover the nose and/or mouth which are used to supply e.g. a pilot, a diver, a firefighter or a hospital patient with a breathing gas mixture. A shell, usually transparent, incorporates at least one tubular orifice to which a gas supply line can be connected. Another type of anatomical mask is used to cover a tracheostomy, an opening in the neck into the trachea, so that a patient can be ventilated otherwise than through the nose and mouth. Other examples of anatomical masks are swimming goggles, industrial dust masks and breathing apparatus, having a shell fitted either with a window or a filter. All of these masks have in common a central, concave component, which may be a relatively hard shell, around the periphery of which is a relatively soft cushion to form an air seal against a particular area of a human or animal body.

At present the central component or shell is made separately from the annular cushion, typically by injection moulding of a plastics material. The cushion, which is to deform to follow the contours of the body, is made typically in a separate injection or blow moulding operation or by rotational casting. It may be a gas injected and/or chemically foamed polymer. Alternatively it may simply be a ring of rubber or other elastomeric polymer. After the two components have been made they must be bonded together. This is usually done by hand.

This three-stage manufacturing procedure is time consuming and labour intensive, which affects the cost of the finished article.

A principal object of the present invention is to speed up and reduce the cost of the manufacturing process, thereby considerably reducing the cost of the finished product while maintaining its quality.

In accordance with one aspect of the present invention there is provided a method of manufacturing an anatomical mask (as herein defined) which comprises forming or placing in a mould a central component of the mask comprising a first, relatively hard polymeric material and introducing into the mould a second relatively soft polymeric material containing a foaming agent to contact and bond to the periphery of the central component.

and opening the mould after the second polymeric material has formed a skin where it contacts the mould but before the second polymeric material has fully solidified whereby the second polymeric material will expand to form a cushion around the periphery of the central component.

Preferably the first polymeric material is transparent polypropylene and the second polymeric material is a thermoplastic elastomer.

Preferably the first polymeric material is allowed at least partially to solidify before exposure to the second polymeric material.

A removable barrier may be placed within the mould to define the periphery of a central area of the mould cavity, the first polymeric material being injected into said central area in a liquid state and allowed to solidify before removal of the barrier and injection into an outer area of the the mould cavity of the second polymeric material in a liquid state.

Methods of manufacturing components made from two or more polymers within the same tool are well known. The use of a removable barrier within the mould to define the periphery of a central area of the mould cavity and effect polymer separation is considered particularly suited to the manufacture of an anatomical mask. However polymer separation can be achieved by indexing parts of the tool after a moulding stage to expose a new cavity region to the moulded component. These manufacturing techniques are well understood in the industry and are therefore not described in more detail.

Gas from a source other than the foaming agent may be introduced into the cushion material before the latter has solidified. Gas may be introduced under pressure into the second polymeric material before its introduction into the mould.

In accordance with another aspect of the present invention there is provided apparatus for use in carrying out the method of the present invention, the apparatus comprising a mould having two parts separable across a cavity defined between the parts when the mould is closed, the cavity having a central, relatively thin area to form the central component of the mask and an outer relatively thicker area into which the second polymeric material will be injected, said two areas being separable by a

removable barrier which, when present in the mould, defines the periphery of the central component of the mask.

The barrier may be tubular and may be movable into or out of the mould through a tubular slot in one of the mould parts.

A preferred embodiment of the present invention will now be described by way of non-limitative example with reference to the accompanying drawings, in which:

Figure 1 illustrates an anaesthetic mask made in accordance with the present invention partially cut away to show internal detail, and

Figures 2-5 are similar sectional elevational views through a mould by which the mask of Figure 1 is made, illustrating successive stages of the manufacturing process.

The injection mould 10 of Figures 2-5 has upper and lower parts 5 and 4 which, when the mould is closed as shown in Figures 2 and 3, define between them a cavity 11. The cavity 11 has at its centre a tubular protrusion 12 into the mould part 5. This will form a gas inlet port 3 for the finished mask 20 (Figure 1). The cavity 11 has a relatively thin central region 7 which will form the shell 13 of the mask and a relatively thicker outer region 9 into which material for the cushion 15 will be injected.

The mould part 4 has a tubular slot 16 in which a tubular metal barrier member 6 is movable. In the closed position of the barrier 6 as shown in Figure 2 it isolates the regions 7 and 9 of the mould cavity 11. When withdrawn as shown in Figure 3 it allows communication between the two regions of the mould cavity.

The manufacturing procedure is as follows. With the barrier 6 closed a polymer such as transparent polypropylene is injected in a liquid state into the central region 7 of the mould cavity until it fills the same. The polymer in the cavity is allowed at least partially to solidify before a second, softer polymer such as a a thermoplastic elastomer is injected in a liquid state into the outer region 9 of the mould cavity. The molten, second polymer will immediately bond to the periphery 8 of the already moulded shell 13 of the mask (Figure 2).

The second, soft polymer injected into the cavity region 9 contains a small proportion of a foaming agent which will release a gas, typically carbon dioxide, when hot. On contact with the relatively cooler mould parts 4,5 the material injected into the outer cavity region 9 forms a skin while its core within the skin remains molten (Figure 3).

The mould is now opened (Figure 4) causing the second, soft polymer to inflate to form the cushion 15 and then the finished mask is ejected from the upper part 5 of the mould (Figure 5).

Injection moulding techniques using a foaming agent to produce differential expansion of different parts of a moulded article are known *per se*, e.g. from WO 97/03800, so that more detailed description is deemed unnecessary. The present invention applies such techniques to the production of an article which has a relatively hard, usually transparent, central component or shell with an annular cushion bonded to its periphery. The shell and cushion are necessarily of different materials giving rise to the production problems referred to in the preamble of this Specification.

The present invention allows the manufacture of anatomical masks to be automated and to be carried out at great speed. Conventional techniques take several minutes, whereas it is believed that masks can be manufactured by the method of the present invention at a rate of one every 20 seconds per tool cavity. This will permit a considerable reduction in the price of anatomical masks with the advantages aforedescribed.

If the inflation of the cushion 15 is deemed insufficient gas can be introduced directly into cavity region 9 during the foaming process. Alternatively gas can be introduced into the polymer melt before injection. Supplementary gas inflation of the cushion 15 may be desirable for many reasons. Less of the expensive foaming agent will be required and gases with higher molecular weights than carbon dioxide, gases less likely to permeate the cushion wall, can be used. These gases have the advantage of reducing the deflation or contraction rate of the cushion. The inflation/deflation characteristics of the cushion may be more precisely controlled.

CLAIMS:

1. A method of manufacturing an anatomical mask (as herein defined) which comprises forming or placing in a mould a central component of the mask comprising a first, relatively hard polymeric material and introducing into the mould a second relatively soft polymeric material containing a foaming agent to contact and bond to the periphery of the central component and opening the mould after the second polymeric material has formed a skin where it contacts the mould but before the second polymeric material has fully solidified whereby the second polymeric material will expand to form a cushion around the periphery of the central component.

2. A method as claimed in claim 1, wherein the first polymeric material is transparent polypropylene and the second polymeric material is a thermoplastic elastomer.

3. A method as claimed in either preceding claim, wherein the first polymeric material is allowed at least partially to solidify before exposure to the second polymeric material.

4. A method as claimed in any one of the preceding claims, wherein a removable barrier is placed within the mould to define the periphery of a central area of the mould cavity, the first polymeric material being injected into said central area in a liquid state and allowed to solidify before removal of the barrier and injection into an outer area of the the mould cavity of the second polymeric material in a liquid state.

5. A method as claimed in any one of the preceding claims, wherein gas from a source other than the foaming agent is introduced into the cushion material before the latter has solidified.

6. A method as claimed in claim 5, wherein a gas is introduced under pressure into the second polymeric material before its introduction into the mould.

7. A method of manufacturing an anatomical mask (as herein defined) substantially as hereinbefore described.

8. Apparatus for use in carrying out the method of any one of the preceding claims, the apparatus comprising a mould having two parts separable across a cavity defined between the parts when the mould is closed, the cavity having a central, relatively thin area to form the central component of the mask and an outer relatively thicker area into which the second polymeric material will be injected, said two areas being separable by a removable barrier which, when present in the mould, defines the periphery of the central component of the mask.

9. Apparatus as claimed in claim 8, wherein the barrier is tubular and is movable into or out of the mould through a tubular slot in one of the mould parts.

10. Apparatus for use in carrying out the method of any one of claims 1-7 substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

11. An anatomical mask (as herein defined) made by the method of any one of claims 1-7 or by means of the apparatus claimed in any one of claims 8-10.

Amendments to the claims have been filed as follows

CLAIMS:

1. A method of manufacturing an anatomical mask (as herein defined) which comprises forming or placing in a mould a central component of the mask comprising a first, relatively hard polymeric material and introducing into the mould a second relatively soft polymeric material containing a foaming agent to contact and bond to the periphery of the central component and opening the mould after the second polymeric material has formed a skin where it contacts the mould but before the second polymeric material has fully solidified whereby the second polymeric material will expand to form a cushion around the periphery of the central component.

2. A method as claimed in claim 1, wherein the first polymeric material is transparent polypropylene and the second polymeric material is a thermoplastic elastomer.

3. A method as claimed in either preceding claim, wherein the first polymeric material is allowed at least partially to solidify before exposure to the second polymeric material.

4. A method as claimed in any one of the preceding claims, wherein a removable barrier is placed within the mould to define the periphery of a central area of the mould cavity, the first polymeric material being injected into said central area in a liquid state and allowed to solidify before removal of the barrier and injection into an outer area of the the mould cavity of the second polymeric material in a liquid state.

5. A method as claimed in any one of the preceding claims, wherein gas from a source other than the foaming agent is introduced into the cushion material before the latter has solidified.

6. A method as claimed in claim 5, wherein a gas is introduced under pressure into the second polymeric material before its introduction into the mould.

7. A method of manufacturing an anatomical mask (as herein defined) substantially as hereinbefore described.

8. Apparatus when used to perform the method of any one of the preceding claims, the apparatus comprising a mould having two parts separable across a cavity defined between the parts when the mould is closed, the cavity having a central, relatively thin area to form the central component of the mask and an outer relatively thicker area into which the second polymeric material will be injected, said two areas being separable by a removable barrier which, when present in the mould, defines the periphery of the central component of the mask.

9. Apparatus as claimed in claim 8, wherein the barrier is tubular and is movable into or out of the mould through a tubular slot in one of the mould parts.

10. Apparatus when used to perform the method of any one of claims 1-7 substantially as hereinbefore described with reference to and as shown in the accompanying drawings.

11. An anatomical mask (as herein defined) made by the method of any one of claims 1-7 or by means of the apparatus claimed in any one of claims 8-10.

Application No: GB 0120066.6
Claims searched: 1-7, 11
Examiner: Monty Siddique
Date of search: 28 December 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T): B5A (AB13, AB14, AB18, AD28, AM5F, AM5X)

Int Cl (Ed.7): A62B (selectively); B29C 44/all 45/14

Other: Online: WPI EPODOC JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB 2328395 A	(MUELLER) opening paragraph of page 7, injection moulding a flexible peripheral portion onto a central rigid portion	
A	GB 2273678 A	(LEACH) page 9 and line 11 etc	
A	GB 1126535	(DESMA-WERKE) expanding mould cavity by moving the plunger 18 to aid expansion of the foam 13	
A	WO 97/03800 A1	(CLARK) controlling foaming	

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.